

REMARKS

Claims 1 and 6-12 were pending in the application. Claims 1 and 6 have been amended. New claims 25-33 have been added. Accordingly, upon entry of the amendments presented herein, claims 1, 6-12 and 25-33 will be pending in the application.

Claim 1 has been amended to specify that monomeric IgA and the agent are linked by chemical conjugation or recombinant genetic fusion. Support for this amendment can be found throughout the specification as originally filed, for example, at page 2, lines 35-37; page 8, lines 22-24; and page 13, lines 1-4.

Claim 6 has been amended to specify that the agent comprises an antibody or an antibody fragment thereof. Support for this amendment can be found throughout the specification as originally filed, for example, at page 12, lines 33-35.

New claim 25 is drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject by administering full-length monomeric IgA linked to an agent which specifically binds the target cell or antigen. Support for new claim 25 can be found throughout the specification as originally filed, for example, at page 2 through page 3, line 2; and page 8, lines 14-26.

New claim 26 is drawn to a method for eliminating a target cell or antigen from the circulatory system of a subject by administering monomeric IgA or a portion of monomeric IgA that binds to Fc α RI, linked to a non-Fc α RI binding agent which specifically binds the target cell or antigen. Support for new claim 26 can be found throughout the specification as originally filed, for example, at page 2, line 27 through page 3, line 11; page 8, lines 14-26; and page 12, lines 33-37.

New claims 27-33 depend from new claim 26. Support for new claims 27-33 can be found throughout the specification as originally filed, for example, in original claims 6-12, respectively.

No new matter has been added. Any amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was performed solely in the interest of expediting prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Acknowledgment of the Examiner's Withdrawal of Prior Rejections

Applicant gratefully acknowledges the Examiner's withdrawal of the previous rejection of claims 1 and 6-12 under 35 U.S.C. § 103(a) as being unpatentable over Shen *et al.* (WO 98/23646) as evidenced by Monteiro *et al.* (*Journal of Experimental Medicine*, 171:597-613, 1990) and the specification.

Rejection of Claims 1, 6, 8 and 11-12 Under 35 U.S.C. § 102(b)

Claims 1, 6, 8 and 11-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mannhalter *et al.* (U.S. Patent 5,808,000, issued 9/15/1998). Specifically, the Examiner states that "Mannhalter *et al.* reads on the claims because the Fc region of monomeric IgA binds FcαRI and the Fc region is linked to an antigen-binding fragment (i.e., Fab fragment), which specifically binds a target cell or antigen (i.e., bacterial or viral)."

Applicant respectfully traverses this rejection. However, to expedite prosecution, independent claim 1 has been amended without prejudice to specify that monomeric IgA or the portion thereof that binds to FcαRI is linked by chemical conjugation or recombinant genetic fusion to the agent. Mannhalter *et al.* neither teach nor suggest chemically linking monomeric IgA to another molecule nor fusing such molecules by genetic recombination. Accordingly, this rejection should be moot.

Rejection of Claims 1, 6 and 8-11 Under 35 U.S.C. § 102(b)

Claims 1, 6, and 8-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by van Spriel *et al.* (*Journal of Infectious Diseases*, 179(3):661-669, 3/3/1999) as evidenced by Van Egmond *et al.* (*Nature Medicine*, 6(6):68-685, June 2000). The Examiner states that van Spriel *et al.* teach "a method of treating a fungal infection in a subject comprising administering a G-CSF followed by injection of a bispecific antibody comprising a FcαRI F(ab) fragment linked to a *C. albicans* directed F(ab')₂ fragments, which effectively enhanced the killing (i.e., elimination) of *C. albicans*." The Examiner relies on Van Egmond *et al.* as teaching that "FcαRI is necessarily present on liver Kupffer cells and the expression of FcαRI is necessarily induced upon administration of G-CSF."

Applicant respectfully traverses this rejection. The claims are drawn to methods which encompass the use of monomeric IgA or a portion of monomeric IgA which binds to FcαRI

linked to an agent. Applicant is not claiming any anti-Fc α RI binding portion, but a specific molecule which is not taught or suggested by the cited reference. In particular, van Spriel *et al.* describe methods of using a bispecific antibody comprising an Fc α RI F(ab) fragment (*i.e.*, a F(ab) fragment of an anti-Fc α RI antibody) linked to a *C. albicans* and fail to teach or suggest using monomeric IgA or a portion of monomeric IgA as claimed. Accordingly, the claims are novel in view of the cited references.

Rejection of Claims 1 and 6-12 Under 35 U.S.C. § 102(e)

Claims 1 and 6-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Deo *et al.* (U.S. Patent 5,922,845, filed 7/11/1996) as evidenced by Van Egmond *et al.* (*Nature Medicine*, 6(6):68-685, June 2000). The Examiner states that Deo *et al.* teach “a method of eliminating an unwanted cell in a subject comprising administering a multispecific molecule comprising an Fc α RI specific antigen-binding fragment (*i.e.*, Fab, Fab', F(ab')₂ Fv or single chain Fv) linked an antibody or antigen-binding fragment thereof that binds a bacteria, virus, fungi or cancer cell, wherein said multispecific molecule is administered by intravenous injection and the method further comprises the administration of G-CSF which enhances the number of Fc α receptors (*i.e.*, Fc α RI).” The Examiner relies on Van Egmond *et al.* as evidencing the expression of Fc α RI on Kupffer cells.

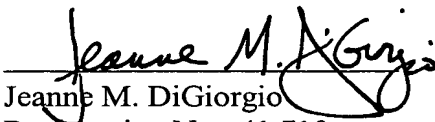
Applicant respectfully traverses this rejection. Like van Spriel *et al.*, Deo *et al.* fail to even mention monomeric IgA, let alone the use of monomeric IgA as claimed. Accordingly, the claims are novel in view of the cited references.

CONCLUSION

In view of the above amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney could be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

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Respectfully submitted,



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